REMARKS/ARGUMENTS

Claims 1, 3, 5-7, 13-27 are pending in the application and presented for examination. Applicants' response filed October 30, 2007 is incorporated herein by reference. Reconsideration is respectfully requested.

Applicants submit herewith a Declaration in support of their earlier amendments and remarks. The Declaration is made by Dr. Hiromu Kondo, Ph.D. an employee of the assignee of the present invention. The Declaration by Dr. Kondo is further evidence that the U.S. Patent No. 5,922,352 ("Chen *et al.*") does not anticipate nor render obvious the present invention.

In paragraph 4, Dr. Kondo declares that "the disclosure of Chen *et al.* and the present invention are very different."

In paragraph 5, Dr. Kondo declares:

> 5. Chen *et al.* teach a tablet having a core and an outer coating. Both the core and the coating contain the same calcium channel blocker drug. According to Chen *et al.*, the core contains a micronized crystalline calcium channel blocker combined with an enteric coating agent. In order to achieve controlled-release of the calcium channel blocker in the colon, the enteric polymer "protects" the calcium channel blocker drug in the low pH environment of the stomach. The external coat is an extended release formulation, which contains the drug and a hydrogel polymer.

In paragraph 6, Dr. Kondo declares:

> 6. The current invention is drawn to a time-release tablet, having two distinct layers each comprising a different formulation. The two distinct layers of the inventive formulation are as follows:
> 1) a core tablet that has a drug and a freely erodible filler, and
> 2) an outer layer made from polyethylene oxide and polyethylene glycol and does not contain the drug.

As such, a skilled artisan would immediately appreciate that the architecture of the tablets are not even similar. However, there is more. In paragraph 7, Dr. Kondo declares:

> 7. Chen *et al.* teach a delayed release enteric coated core to protect against a pH change, whereas the inventive timed-release tablet means that after a specific lag time, the drug from the pharmaceutical

> preparation is released. In the present invention, timed-release is achieved by the specific formulation of the core tablet and outer layer.

But, as Dr. Kondo makes clear in paragraph 8, delayed release and timed-release are not the same.

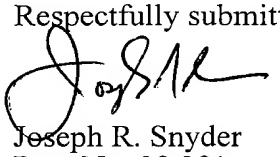
> 8. Technically speaking, a delayed release mechanism is much different than a time release mechanism. The delayed release of the cited art is achieved through the use of an enteric coat. The timed-release of the present invention is achieved by the formulation of the a freely erodible filler of the core tablet and the outer layer. Neither the core-tablet layer of the inventive formulation or the outer layer contain enteric polymers.

Based on his scientific opinion, Dr. Kondo declares in paragraph 9:

> 9. As such, it is my scientific opinion that all the limitation of the present claims are not found in Chen *et al.* and thus, the claims are not anticipated, nor rendered obvious.

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



Joseph R. Snyder
Reg. No. 39,381

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 925-472-5000
Fax: 415-576-0300
JS:js

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No. 3651
Toyohiro Sawada *et al.*	Examiner: Micah Paul Young
Application No.: 09/834,410	Technology Center/Art Unit: 1618
Filed: April 12, 2001	DECLARATION
For: TIMED-RELEASE COMPRESSION-COATED SOLID COMPOSITION FOR ORAL ADMINISTRATION	
Customer No.: 20350	

I, Hiromu Kondo, Ph.D. being duly warned that willful false statements and the like are punishable by fine or imprisonment or both, under 18 U.S.C. § 1001, and may jeopardize the validity of the patent application or any patent issuing thereon, state and declare as follows:

1. I am a citizen of Japan, and I have received a Ph.D. degree in 2003 from Nihon University. My *Curriculum Vitae* is attached as an Exhibit.

2. I have been employed by Astellas Pharma Inc. (formally Yamanouchi Pharmaceutical Co., Ltd., the assignee of the present invention) since April 5, 1993.

3. I have been engaged in research and development regarding pharmaceutical preparations, especially oral dosage forms, since joining Astellas Pharma Inc.

4. I have reviewed and analyzed the Office Action dated June 4, 2007 in the above-identified application. It is my understanding that the Examiner has rejected certain claims allegedly being anticipated by U.S. Patent No. 5,922,352 ("Chen *et al.*"). From a technical point of view, the disclosure of Chen *et al.* and the present invention are very different.

5. Chen *et al.* teach a tablet having a core and an outer coating. Both the core and the coating contain the same calcium channel blocker drug. According to Chen *et al.*,

the core contains a micronized crystalline calcium channel blocker combined with an enteric coating agent. In order to achieve controlled-release of the calcium channel blocker in the colon, the enteric polymer "protects" the calcium channel blocker drug in the low pH environment of the stomach. The external coat is an extended release formulation, which contains the drug and a hydrogel polymer.

6. The current invention is drawn to a time-release tablet, having two distinct layers each comprising a different formulation. The two distinct layers of the inventive formulation are as follows:

1) a core tablet that has a drug and a freely erodible filler, and

2) an outer layer made from polyethylene oxide and polyethylene glycol and does not contain the drug.

7. Chen *et al.* teach a delayed release enteric coated core to protect against a pH change, whereas the inventive timed-release tablet means that after a specific lag time, the drug from the pharmaceutical preparation is released. In the present invention, timed-release is achieved by the specific formulation of the core tablet and outer layer.

8. Technically speaking, a delayed release mechanism is much different than a time release mechanism. The delayed release of the cited art is achieved through the use of an enteric coat. The timed-release of the present invention is achieved by the formulation of the a freely erodible filler of the core tablet and the outer layer. Neither the core-tablet layer of the inventive formulation or the outer layer contain enteric polymers.

9. As such, it is my scientific opinion that all the limitation of the present claims are not found in Chen *et al.* and thus, the claims are not anticipated, nor rendered obvious.

The declarant has nothing further to say.

Hiromu Kondo
Hiromu Kondo, Ph.D.

November 22, 2007
Date